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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,236	GANS, ARNOLD M.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *32-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/03*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *1/22/07*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of Applicant's Response to Restriction/Election requirement filed 01/26/07, the Preliminary Amendment filed 2/27/06 and the Information Disclosure Statement (IDS) filed 12/19/03 is acknowledged.

Applicant's election of Group I (claims 1-31) in the reply filed on 1/26/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 32-58 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-58 are pending in this action. Claims 32-58 have been withdrawn (based on non-elected subject matter). Claims 1-31 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 10, 18 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 9 recites the limitation, "*...said composition comprising the essential amino acids required by said mammal*". The claim is indefinite because it is unclear as to which particular (essential) amino acids Applicant is referring to and which (essential) amino acids are required in the composition.

Moreover, there is lack of antecedent basis for the limitation "the essential amino acids" in the claim.

Claim 10 is indefinite because the claim limitation "*wherein the composition is administered in addition to the generally accepted standard treatment for decubitus ulcers*" does not clearly set forth what the "generally accepted standard treatment" is comprised of. The claim is rather vague and confusing as to what exactly the treatment steps encompass. Clarification is requested.

Claim 18, lines 1-2 recites the limitation, "*wherein the amount ingested is about 30 mL...*". The claim is indefinite because it is unclear as to what component Applicant is referring to when reciting the limitation "wherein the amount ingested is about 30 mL...". The claim does not point out what exactly is being ingested. If Applicant is referring to the amount of protein composition being ingested, then the claim should set forth language such as "...the amount ingested of said protein composition". At present, the claim is vague as to what ingredient is being ingested.

Clarification is requested.

Claim 24 recites the limitation, "...*said composition comprising the essential amino acids required by said mammal*". The claim is indefinite because it is unclear as to which particular (essential) amino acids Applicant is referring to and which (essential) amino acids are required in the composition.

Moreover, there is lack of antecedent basis for the limitation "the essential amino acids" in the claim.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 4,025,650 ('650 Patent) in view of Barbul *et al.* (U.S. Patent No. 5,733,884) (the '884 Patent). Although the conflicting claims are

not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant application and '650 Patent.

It is noted that the instant application is drawn to a method of treating a mammal (to promote wound healing) whereas claims 1 and 2 of the '650 Patent are drawn to a nutritional composition. However, both the claims of the instant application and the '650 Patent encompass a nutritional protein composition having the same components. Namely, both the instant application and the '650 Patent claim a composition comprising hydrolyzed gelatin, tryptophan, a sweetener and an ingestible carrier.

The secondary reference of Barbul *et al.* ('884 Patent) is relied upon for the teaching of the correlation between maintaining adequate nutrition and the promotion of wound healing. The '884 Patent teaches that the success of wound healing is dependent on many interrelated factors; the most important factor in treating wound healing is providing adequate nutrition and avoiding malnutrition. The reference goes on to teach that wound healing depends, in part, on adequate nutrition provided by a well balanced diet of protein, carbohydrate, fat, vitamins, minerals, trace elements and water (see column 1, lines 52-62).

While the amounts of tryptophan claimed are different in the instant application (about 0.02 to about 2.0 parts by weight) versus the tryptophan claimed in the '650 Patent (about 0.02 to about 0.75 parts by weight) and the amounts of certain amino acids claimed are different, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to determine suitable amounts of each component (i.e., amino acids) through the use of routine or manipulative experimentation with the expectation of obtaining optimal results.

* * * * *

Claims 1-3, 9, 10 and 15-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 4,042,688 ('688 Patent) in view of Barbul *et al.* (U.S. Patent No. 5,733,884) (the '884 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant application and '688 Patent.

It is noted that the instant application is drawn to a method of treating a mammal (to promote wound healing) whereas claims 1-7 of the '688 Patent are drawn to a method of providing rapid body build-up. However, both the claims of the instant application and the '688 Patent encompass a high-protein nutritional composition comprised of the same components. Namely, both the instant application and the '688 Patent claim a composition comprising hydrolyzed gelatin, tryptophan, a sweetener and an ingestible carrier. In addition, the '688 Patent provides a method which aids in the process of body build-up before surgery and of tissue repair after surgery (see Abstract) and thus is directed to wound healing methods.

The secondary reference of Barbul *et al.* ('884 Patent) is relied upon for the teaching of the correlation between maintaining adequate nutrition and the promotion of wound healing. The

'884 Patent teaches that the success of wound healing is dependent on many interrelated factors; the most important factor in treating wound healing is providing adequate nutrition and avoiding malnutrition. The reference goes on to teach that wound healing depends, in part, on adequate nutrition provided by a well balanced diet of protein, carbohydrate, fat, vitamins, minerals, trace elements and water (see column 1, lines 52-62).

While the amounts of tryptophan claimed are different in the instant application (about 0.02 to about 2.0 parts by weight) versus the tryptophan claimed in the '688 Patent (about 0.02 to about 0.75 parts by weight) and the amounts of certain amino acids claimed are different, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to determine suitable amounts of each component (i.e., amino acids) through the use of routine or manipulative experimentation with the expectation of obtaining optimal results.

* * * * *

Claims 1-3 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 4,053,589 ('589 Patent) in view of Barbul *et al.* (U.S. Patent No. 5,733,884) (the '884 Patent). Although the conflicting

claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant application and '589 Patent.

It is noted that the instant application is drawn to a method of treating a mammal (to promote wound healing) whereas claims 1-4 of the '589 Patent are drawn to a method of treating nutritional deficiency during cardiac cachexia, diabetes, hypoglycemia, gastroenterology, skin conditions related to lipid, cell glycogen and keratin deficiencies and alcoholishm. However, both the claims of the instant application and the '589 Patent encompass a high-protein nutritional composition comprised of the same components. Namely, both the instant application and the '589 Patent claim a composition comprising hydrolyzed gelatin, tryptophan, a sweetener and an ingestible carrier. The '589 Patent provides a method of treating skin conditions, which would encompass wound healing.

The secondary reference of Barbul *et al.* ('884 Patent) is relied upon for the teaching of the correlation between maintaining adequate nutrition and the promotion of wound healing. The '884 Patent teaches that the success of wound healing is dependent on many interrelated factors; the most important factor in treating wound healing is providing adequate nutrition and avoiding malnutrition. The reference goes on to teach that wound healing depends, in part, on adequate nutrition provided by a well balanced diet of protein, carbohydrate, fat, vitamins, minerals, trace elements and water (see column 1, lines 52-62).

While the amounts of tryptophan claimed are different in the instant application (about 0.02 to about 2.0 parts by weight) versus the tryptophan claimed in the '589 Patent (about 0.02 to about 0.75 parts by weight) and the amounts of certain amino acids claimed are different, the Examiner points out that generally, differences in concentration will not support the patentability

of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to determine suitable amounts of each component (i.e., amino acids) through the use of routine or manipulative experimentation with the expectation of obtaining optimal results.

* * * * *

Claims 1-3 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 4,042,687 ('687 Patent) in view of Barbul *et al.* (U.S. Patent No. 5,733,884) (the '884 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant application and '687 Patent.

It is noted that the instant application is drawn to a method of treating a mammal (to promote wound healing) whereas claims 1-4 of the '687 Patent are drawn to a method of treating obesity. However, both the claims of the instant application and the '687 Patent encompass a high-protein nutritional composition comprised of the same components. Namely, both the instant application and the '687 Patent claim a composition comprising hydrolyzed gelatin, tryptophan, a sweetener and an ingestible carrier.

The secondary reference of Barbul *et al.* ('884 Patent) is relied upon for the teaching of the correlation between maintaining adequate nutrition and the promotion of wound healing. The '884 Patent teaches that the success of wound healing is dependent on many interrelated factors; the most important factor in treating wound healing is providing adequate nutrition and avoiding malnutrition. The reference goes on to teach that wound healing depends, in part, on adequate nutrition provided by a well balanced diet of protein, carbohydrate, fat, vitamins, minerals, trace elements and water (see column 1, lines 52-62).

While the amounts of tryptophan claimed are different in the instant application (about 0.02 to about 2.0 parts by weight) versus the tryptophan claimed in the '687 Patent (about 0.02 to about 0.75 parts by weight) and the amounts of certain amino acids claimed are different, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to determine suitable amounts of each component (i.e., amino acids) through the use of routine or manipulative experimentation with the expectation of obtaining optimal results.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-13 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gans *et al.* (U.S. Patent No. 4,025,650).

The instant invention is drawn to a method of treating a mammal to promote wound healing in said mammal in need thereof, comprising orally administering to said mammal an effective amount of a concentrated protein composition comprising about 5 to about 75 parts by weight of enzymatically hydrolyzed gelatin, about 0.02 to about 2.0 parts by weight of tryptophan, about 0.1 to about 2 parts by weight of a sweetener and about 5 to about 100 parts by weight of an ingestible carrier, said composition comprising the essential amino acids required by said mammal.

Gans *et al.* ('650) disclose a method for providing high-protein nutrition which comprises ingestion of a pre-digested protein composition containing all of the essential amino acids and having a palatable taste and odor (see Abstract).

The method of improving nutrition comprises administering an orally-ingestible, predigested protein composition comprising a sweet-tasting and readily ingestible gelatin hydrolysate formulation containing all of the essential amino acids and being free of undesirable triglycerides and fats (col. 3, lines 16-21).

In its liquid form, the invention comprises an *aqueous* ((carrier) about 5 to about 100 parts by weight) composition, preferably containing a *gelatin hydrolysate* (about 5 to about 75 parts by weight) made by hydrolyzing animal collagen, preferably collagen derived from the skin of pork bellies by means of enzymatic hydrolysis; a *sweetener*, such as sorbitol (about 0.1 to about 2 parts by weight); a palatable acid; *trytophane* (about 0.02 to about 0.75 parts by weight) a synthetic sweetener; flavoring and coloring agents; and *preservatives*, used for stabilizing purposes (col. 3, lines 22-45); Claim 1.

The preferred enzymes used in the hydrolysis are bromolin and papain (col. 3, lines 46-48). Other enzymes that can also be used include pepsin and trypsin (col. 3, lines 49-50).

Tryptophane is added in an amount of from about 0.02 to about 0.75 parts by weight of the composition (col. 3, lines 51-57).

Artificial sweeteners for use in the composition are also taught and include sodium saccharin (col. 3, lines 58-68). Natural sweeteners are disclosed and include sorbitol (col. 4, lines 1-17).

The nutritional composition can be useful in treating skin disorders related to lipid, cell glycogen or keratin deficiencies since it provides a nutritionally satisfactory diet without fats and oils and improves the formation of keratin by amino acid supplementation (col. 8, lines 40-58).

The liquid compositions of the invention are illustrated in the Tables and Examples shown at column 4, line 20 – col. 9, line 12. Example 1 at column 4, line 55 – column 5, line 60 demonstrates preparation of the nutritional composition. A listing of amino acids present in the composition is shown at column 5, lines 15-32.

The instant claims are anticipated by the '650 Patent.

Claims 1, 3-13, 15-17 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gans *et al.* (U.S. Patent No. 4,042,688).

The instant invention is drawn to a method of treating a mammal to promote wound healing in said mammal in need thereof, comprising orally administering to said mammal an effective amount of a concentrated protein composition comprising about 5 to about 75 parts by weight of enzymatically hydrolyzed gelatin, about 0.02 to about 2.0 parts by weight of tryptophan, about 0.1 to about 2 parts by weight of a sweetener and about 5 to about 100 parts by weight of an ingestible carrier, said composition comprising the essential amino acids required by said mammal.

Gans *et al.* ('688) disclose a method for providing high-protein nutrition which comprises ingestion of a pre-digested protein composition containing all of the essential amino acids and having a palatable taste and odor (see Abstract).

The method of improving nutrition comprises administering an orally-ingestible, predigested protein composition comprising a sweet-tasting and readily ingestible gelatin hydrolysate formulation containing all of the essential amino acids and being free of undesirable triglycerides and fats (col. 3, lines 16-21).

In its liquid form, the invention comprises an *aqueous* ((carrier) about 5 to about 100 parts by weight) composition, preferably containing a *gelatin hydrolysate* (about 5 to about 75 parts by weight) made by hydrolyzing animal collagen, preferably collagen derived from the skin of pork bellies by means of enzymatic hydrolysis; a *sweetener*, such as sorbitol (about 0.1 to

about 2 parts by weight); a palatable acid; *trytophane* (about 0.02 to about 0.75 parts by weight) a synthetic sweetener; flavoring and coloring agents; and *preservatives*, used for stabilizing purposes (col. 3, lines 22-45); Claim 1.

The preferred enzymes used in the hydrolysis are bromolin and papain. Other enzymes that can also be used include pepsin and trypsin (col. 3, lines 48-52).

Tryptophane is added in an amount of from about 0.02 to about 0.75 parts by weight of the composition (col. 3, lines 51-57).

Artificial sweeteners for use in the composition are also taught and include sodium saccharin (col. 3, lines 60-68). Natural sweeteners are disclosed and include sorbitol (col. 4, lines 1-19).

The method of the reference provides high-protein nutrition such as to aid the process of body build-up before surgery and of tissue repair after surgery or in other situations where rapid body build-up is desirable (Abstract). Thus, the instant method of treating a mammal (to promote wound healing) would be inherent in the disclosure of the '688 Patent, since the nutritional composition can be taken before and after surgery to help in the repair process of tissue.

The nutritional composition can also be useful in treating skin disorders related to lipid, cell glycogen or keratin deficiencies since it provides a nutritionally satisfactory diet without fats and oils and improves the formation of keratin by amino acid supplementation (col. 8, lines 46-50).

The liquid compositions of the invention are illustrated in the Tables and Examples shown at column 4, line 20 – col. 9, line 5. Example 1 at column 4, line 25 – column 5, line 60

demonstrates preparation of the nutritional composition. A listing of amino acids present in the composition is shown at column 5, lines 15-32.

The instant claims are anticipated by the '688 Patent.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gans *et al.* (U.S. Patent No. 4,025,650) OR Gans *et al.* (U.S. Patent No. 4,042,688) in view of Kamarei (5,985,339) and further in view of Barbul *et al.* (U.S. Patent No. 5,733,884).

Gans *et al.* ('650), as delineated above, teach a method for providing high-protein nutrition which comprises ingestion of a pre-digested protein composition containing all of the essential amino acids and having a palatable taste and odor (see Abstract).

The method of improving nutrition comprises administering an orally-ingestible, predigested protein composition comprising a sweet-tasting and readily ingestible gelatin hydrolysate formulation containing all of the essential amino acids and being free of undesirable triglycerides and fats (col. 3, lines 16-21).

In its liquid form, the invention comprises an *aqueous* ((carrier) about 5 to about 100 parts by weight) composition, preferably containing a *gelatin hydrolysate* (about 5 to about 75 parts by weight) made by hydrolyzing animal collagen, preferably collagen derived from the skin of pork bellies by means of enzymatic hydrolysis; a *sweetener*, such as sorbitol (about 0.1 to about 2 parts by weight); a palatable acid; *trytophane* (about 0.02 to about 0.75 parts by weight) a synthetic sweetener; flavoring and coloring agents; and *preservatives*, used for stabilizing purposes (col. 3, lines 22-45); Claim 1.

The preferred enzymes used in the hydrolysis are bromolin and papain (col. 3, lines 46-48). Other enzymes that can also be used include pepsin and trypsin (col. 3, lines 49-50).

Tryptophane is added in an amount of from about 0.02 to about 0.75 parts by weight of the composition (col. 3, lines 51-57).

Artificial sweeteners for use in the composition are also taught and include sodium saccharin (col. 3, lines 58-68). Natural sweeteners are disclosed and include sorbitol (col. 4, lines 1-17).

The nutritional composition can be useful in treating skin disorders related to lipid, cell glycogen or keratin deficiencies since it provides a nutritionally satisfactory diet without fats and oils and improves the formation of keratin by amino acid supplementation (col. 8, lines 40-58).

The liquid compositions of the invention are illustrated in the Tables and Examples shown at column 4, line 20 – col. 9, line 12. Example 1 at column 4, line 55 – column 5, line 60 demonstrates preparation of the nutritional composition. A listing of amino acids present in the composition is shown at column 5, lines 15-32.

Gans *et al.* ('688), as delineated above, teach a method for providing high-protein nutrition which comprises ingestion of a pre-digested protein composition containing all of the essential amino acids and having a palatable taste and odor (see Abstract).

The method of improving nutrition comprises administering an orally-ingestible, predigested protein composition comprising a sweet-tasting and readily ingestible gelatin hydrolysate formulation containing all of the essential amino acids and being free of undesirable triglycerides and fats (col. 3, lines 16-21).

In its liquid form, the invention comprises an *aqueous* ((carrier) about 5 to about 100 parts by weight) composition, preferably containing a *gelatin hydrolysate* (about 5 to about 75 parts by weight) made by hydrolyzing animal collagen, preferably collagen derived from the skin of pork bellies by means of enzymatic hydrolysis; a *sweetener*, such as sorbitol (about 0.1 to about 2 parts by weight); a palatable acid; *trytophane* (about 0.02 to about 0.75 parts by weight)

a synthetic sweetener; flavoring and coloring agents; and *preservatives*, used for stabilizing purposes (col. 3, lines 22-45); Claim 1.

The preferred enzymes used in the hydrolysis are bromolin and papain. Other enzymes that can also be used include pepsin and trypsin (col. 3, lines 48-52).

Tryptophane is added in an amount of from about 0.02 to about 0.75 parts by weight of the composition (col. 3, lines 51-57).

Artificial sweeteners for use in the composition are also taught and include sodium saccharin (col. 3, lines 60-68). Natural sweeteners are disclosed and include sorbitol (col. 4, lines 1-19).

The method of the reference provides high-protein nutrition such as to aid the process of body build-up before surgery and of tissue repair after surgery or in other situations where rapid body build-up is desirable (Abstract). Thus, the instant method of treating a mammal (to promote wound healing) would be inherent in the disclosure of the '688 Patent, since the nutritional composition can be taken before and after surgery to help in the repair process of tissue.

The nutritional composition can also be useful in treating skin disorders related to lipid, cell glycogen or keratin deficiencies since it provides a nutritionally satisfactory diet without fats and oils and improves the formation of keratin by amino acid supplementation (col. 8, lines 46-50).

The liquid compositions of the invention are illustrated in the Tables and Examples shown at column 4, line 20 – col. 9, line 5. Example 1 at column 4, line 25 – column 5, line 60

demonstrates preparation of the nutritional composition. A listing of amino acids present in the composition is shown at column 5, lines 15-32.

Gans *et al.* ('650) and Gans *et al.* ('688) do not teach treatment of decubitus ulcers and do not teach sucralose as the artificial sweetener.

Kamarei ('339) teaches a ready-to-drink nutritional composition comprising essential nutrients, enzymatically-hydrolyzed proteins, amino acids and combinations thereof comprising artificial sweeteners, such as *sucralose* and teach that the compositions are useful for people recovering from illness, general surgery or patients undergoing wound healing, e.g., *decubitus ulcers* (see column 12, lines 38-63); (col. 15, lines 29-32); (cols. 19-22); (Claims 51, 57 and 62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a nutritional composition, useful for wound healing, such as to treat decubitus ulcers as well as incorporate an artificial sweetener, such as sucralose, as taught by Kamarei, within the methods and formulations of Gans et al. ('650) & ('688). One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Kamarei teaches that their nutritional compositions are highly effective for people recovering from illness, general surgery or patients undergoing wound healing, e.g., decubitus ulcers, since they comprise a high-protein, amino acid and nutrient formulation and also teach sucralose, used as an effective sweetener to enhance the organoleptic and sweetness quality of the compositions. The expected result would be an enhanced and palatable nutritional composition, useful in the treatment of wounds.

With regards to the claimed amounts of each component, no unexpected results have been observed through the clamed amounts. It would have been obvious to determine suitable or effective amounts through the use of routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regards to the claim limitation "to promote wound healing", the Examiner notes that this limitation is a future-intended use limitation, which does not afford patentable weight to the claims. Nonetheless, the prior art recognizes methods of tissue repair and improving skin conditions by administering nutritional compositions composed of essentially the same components as that claimed by Applicant. It is obvious to one of ordinary skill in the art that the wound healing process is based significantly on nutritional intake. Such is also evident from the reference of Barbul *et al.* ('884) (see below).

The **Barbul *et al.* ('884)** Patent is relied upon for the teaching of the correlation between maintaining adequate nutrition and the promotion of wound healing. The '884 Patent teaches that the success of wound healing is dependent on many interrelated factors; the most important factor in treating wound healing is providing adequate nutrition and avoiding malnutrition. The reference goes on to teach that wound healing depends, in part, on adequate nutrition provided

by a well balanced diet of protein, carbohydrate, fat, vitamins, minerals, trace elements and water (see column 1, lines 52-62).

Thus, It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer a nutritional composition that meets the nutritional requirement of patients with wounds, because Barbul *et al.* teach such a composition and teach that the success of wound healing is dependent on many interrelated factors; the most important factor in treating wound healing is providing adequate nutrition and avoiding malnutrition. The expected result would be a highly effective nutritional composition that aids in the healing process of tissue repair and the treatment of wounds.

Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Humera N. Sheikh

Primary Examiner

Art Unit 1615

April 15, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER

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